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APPLICATION NO	FILING DATE	FIRST NAME INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 407,605	09 28 1999	ALLAN M. MILLER	10278 009001	2966

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225 FRANKLIN ST  
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

055

DATE MAILED 03 05 2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/407,605

Examiner

Chih-Min Kam

Applicant(s)

MILLER ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 81-94, 96-108 and 110 is/are ~~allowed~~ free of prior art.
- 6) ☐ Claim(s) 64-79, 111-120, 122-125, 127-130 and 132-135 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

### Attachments:

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Status of the Claims*

1. Claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 are pending.

Applicants' amendment filed December 18, 2002 (Paper No. 22) is acknowledged, and applicants' response has been fully considered. Claims 64, 69, 73, 81, 85, 89, 97, 100, 103, 113, 114, 116, 119, 120, 125, 130 and 135 have been amended, and claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 are examined.

### *Objection Withdrawn*

2. The previous objection of claims 64-79, 81-94, 96-108, 110-115, 119, 120, 122-125, 127-130 and 132-135 regarding citing "Table 1", is withdrawn in view of applicants' amendment to the claim and applicants' response at page 8 in Paper No. 22.

### *Rejection Withdrawn*

### *Claim Rejections - 35 USC § 112*

3. The previous rejection of claims 116-118 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 8-9 in Paper No. 22.

### *Claim Rejections - 35 USC § 102*

4. The previous rejection of claims 64-66, 68-71, 111 and 112 under 35 U.S.C. 102(a) as anticipated by Kim *et al.* (Gene 199, 293-301 (October 1997)), is withdrawn in view of applicants' response at pages 9-11 in Paper No. 22.

### *Claim Rejections - Obviousness - Two Doubly Patenting*

provisional patent policy (a policy reflected in the statute) so as to prevent the acquisition of

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 64-79, 111-120, 122-125, 127-130 and 132-135 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending application No. 09/686,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 64-79, 111-120, 122-125, 127-130 and 132-135 in the instant application discloses a synthetic nucleic acid sequence which encodes a human protein wherein non-common codons or less-common codons are replaced with codons, a method of preparing the nucleic acid, a vector comprising the nucleic acid, and mammalian cells transformed with the nucleic acid. This is obvious in view of claims 1-15 of copending application which discloses a synthetic nucleic acid which encodes  $\alpha$ -galactosidase, which is not limited to a specific species, wherein non-common codons or less-common codons are replaced with codons, a vector comprising the nucleic acid, a cell transformed with the nucleic acid, and a method of preparing the nucleic acid. Thus, claims 64-79, 111-120, 122-125, 127-130 and 132-135 in present application and claims 1-15 of copending application are obvious variations of a synthetic nucleic acid sequence which encodes a human

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replaced with codons, a method of preparing the nucleic acid, and mammalian cells transformed with the nucleic acid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 64, 65, 68-71, 73, 74, 76-79, 113-115 and 119 are rejected under 35 U.S.C. 102(a) as anticipated by Coleman *et al.* (WO 98/24922).

Coleman *et al.* disclose a synthetic gene (SEQ ID NO:4, 462 base pairs) encoding human insulin-like growth factor (SEQ ID NO:5, 153 amino acid residues) wherein all non-preferred or less preferred codons in the natural gene (SEQ ID NO:1) have been replaced by common codons (153 codons; pages 42-43; claims 64, 65, 68, 69-71, 73, 74, 76-79, 113-115 and 119). Optimal codons usage in humans is indicated by codon usage frequency for highly expressed human gene is shown in Fig. 9, and the alignment of optimized IGF-1 sequence and natural sequence in

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7. Claims 64, 65, 68-71, 73, 74, 76-79, 113-115 and 119 are rejected under 35 U.S.C. 102(e) as anticipated by Ralston *et al.* (U. S. Patent 6,034,072).

Ralston *et al.* disclose a synthetic gene (SEQ ID NO:2, 462 base pairs) encoding human IL-2 (SEQ ID NO:3, 153 amino acid residues) wherein all non-preferred or less preferred codons in the natural gene (SEQ ID NO:1) have been replaced by common codons (153 codons; columns 20-21; claims 64, 65, 68, 69-71, 73, 74, 76-79, 113-115 and 119), and optimal codon usage in humans is indicated by codon usage frequency for highly expressed human gene is shown in Fig. 5.

### ***Conclusion***

8. Claims 64-79, 111-120, 122-125, 127-130 and 132-135 are rejected. It appears claims 81-94, 96-108 and 110 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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March 1, 2003